

APR 19 2004

Appendix G

510(k) Summary

Submitter:	NeoMetrics, Inc. 14800 28 th Ave. N., Suite 150 Plymouth, MN 55447
Contact Person:	Gene Champeau President 763-559-4440 (voice) 763-559-7676 (fax)
Date Prepared:	March XX, 2004
Trade Name:	VascuPuncture™ PICC Guidewire with Hydro-Silk Coating
Classification Name and Number:	Wire, Guide, Catheter: 21 CFR 870.1330
Product Code:	DQX
Predicate Device Name and 510(k) Number	VascuPuncture PICC Guidewire, K031652, dated September 30, 2003.
Device Description:	<u>DEVICE DESCRIPTION</u> The VascuPuncture™ PICC Guidewires are guidewires constructed of stainless steel and nickel titanium alloy with a lubricious coating. Devices are available in diameters of 0.014 and 0.018 inches and in lengths ranging from 45 to 145 cm.
Intended Use:	The VascuPuncture PICC Guidewire is indicated for percutaneous entry of peripheral vessels using the Seldinger Technique. VascuPuncture Guidewires are not indicated for use in the coronary or cerebral vasculature.
Statement of Technological Comparison	Functional and performance characteristics are demonstrated through equivalence with the predicate device and testing of representative device samples. Biocompatibility is demonstrated through equivalence with legally marketed predicate devices and the result of biocompatibility testing.
Conclusion:	VascuPuncture™ PICC Guidewire with Hydro-Silk Coating is substantially equivalent to the VascuPuncture™ PICC Guidewire. This conclusion is based upon the fact that this device is substantially equivalent to the predicate device in terms of functional design, indications for use, principles of operation and performance characteristics.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 19 2004

NeoMetrics, Inc.
c/o Mr. Gene Champeau
President
14800 28th Ave. N., Suite 150
Plymouth, MN 55447

Re: K040786
VascuPuncture™ PICC Guidewire with Hydro-Silk Coating
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: March 24, 2004
Received: March 29, 2004

Dear Mr. Champeau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

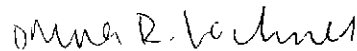
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040786

Device Name: VascuPuncture PICC Guidewire with Hydro-Silk Coating

Indications For Use: The VascuPuncture PICC Guidewire is indicated for percutaneous entry of peripheral vessels using the Seldinger technique. VascuPuncture Guidewires are not indicated for use in the coronary or cerebral vasculature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Lochner
(Division Sign-Off)
Division of Cardiovascular Devices

Device Number K040786

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